REMARKS

I. Status of the Claims

Claims 1-4, 6, and 20-25 are under examination.

Claim 1 has been amended to recite "an antibody generated using a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2 as an immunogen, for regulating bone-forming activity in a mammal." Support for this amendment may be found throughout the specification and in particular in original claim 1, and in paragraphs 12, 47, and 103-106 of the published application (U.S. Patent Application No. 20040115195).

Claims 20 and 22-24 have also been amended to recite that the antibody is generated using frizzled related protein-1 (sFRP-1) of SEQ ID NO:2, or specific fragments thereof as an immunogen and that the antibody is capable of inhibiting cell death mediated by overexpression of the polynucleotide set forth in SEQ ID NO:1. Support for this amendment may be found throughout the specification and in particular in Examples 12-14 and Figs. 9-10 and 12, of the published application (U.S. Patent Application No. 20040115195).

No new matter has been added.

IV. Claim Rejections

A. Rejections under 35 U.S.C. §112, first paragraph; Enablement

Claims 20-24 remain rejected under 35 U.S.C. §112, first paragraph as allegedly lacking full enablement. In order to expedite prosecution of the present case, and without conceding the Examiner's position or the validity of the rejection, Applicant has amended claim 20 to recite "at least one antibody generated using a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2 as an immunogen and wherein the antibody is capable of inhibiting cell death mediated by overexpression of the polynucleotide set forth in SEQ ID NO:1." Claims 22-24 have been similarly amended to recite that the antibody is generated using specific fragments of sFRP-1 protein of SEQ ID NO: 2 as an immunogen. Support for these amendments may be found throughout the specification and in particular in Examples 12-14 and Figs. 9-10 and 12, of the published application (U.S. Patent Application No. 20040115195).

The amended claims are fully enabled for generating an antibody using a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2, or the specified fragments as an immunogen and require that the antibody is capable of inhibiting cell death mediated by overexpression of the polynucleotide set forth in SEQ ID NO:1. Example 12 describes an anti-peptide antisera generated using an amino acid fragment of SEQ ID NO:2 that inhibits cell death mediated by overexpression of the polynucleotide set forth in SEQ ID NO:1. Thus, anyone skilled in the art is capable of generating similar antibodies as claimed, according to the methods and examples using the specified protein fragments followed by screening for the desired ability of inhibiting cell death mediated by overexpression of the claimed sFRP-1 polynucleotide sequence, as described in the specification.

Thus, Applicant submits that the rejections under 35 U.S.C. § 112, first paragraph, have been obviated and respectfully requests that these rejections be withdrawn.

B. Rejections under 35 U.S.C. §102(e)

Claims 1, 3-4, 6, and 20-25 have been rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 6,433,155 ("Umansky"). The Examiner asserts that Umansky discloses a pharmaceutical composition comprising an antibody against a polypeptide of the SARP (secreted apoptosis related protein) family that includes murine msarp1, as well as human hsarp1, hsarp2, and hsarp3. (*See*, Office Action, page 5).

According to the Examiner, SARP-2 is also known as sFRP-1 and shares 99.7% similarity to the sFRP protein of SEQ ID NO:2 of the present application and exhibits 100% identity to amino acids 217-231 of SEQ ID NO:2. The Examiner admits that Umansky does not expressly teach pharmaceutical compositions for regulating bone-forming activity in a mammal. The Examiner concludes, however, that this function would be inherent in the composition, since it allegedly has exactly the same components recited in the claims. The Examiner further concludes that the preamble "for regulating bone-forming activity is not given weight, since the composition is the same." (*See*, Office Action, page 6).

Anticipation requires that each and every element of the rejected claim(s) be disclosed in a single prior art reference. *See* MPEP § 2131 (8th Ed., Rev. 4, Jan. 2006). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently

described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

In order to expedite prosecution of the present case, and without conceding the Examiner's position or the validity of the rejection, claim 1 has been amended to recite "an antibody generated using a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2 as an immunogen for regulating bone-forming activity in a mammal," as described above. Claim 20 has been similarly amended to recite "at least one antibody generated using a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2 as an immunogen and that the antibody is capable of inhibiting cell death mediated by overexpression of the polynucleotide set forth in SEQ ID NO:1." Claims 22-24 have been similarly amended to recite that the antibody is generated using specific fragments of sFRP-1 protein of SEQ ID NO: 2. Support for these amendments may be found throughout the specification and in particular in original claim 1 and in paragraphs 12, 47, and 103-106, and in Examples 12-14, and Figs. 9-10 and 12, of the published application (U.S. Patent Application No. 20040115195).

The SARP proteins described by Umansky are not identical to the sFRP-1 protein of SEQ ID NO:2. Thus, Umansky cannot anticipate antibodies generated using an sFRP-1 protein of SEQ ID NO:2 as an immunogen. Additionally, Umansky does not teach a pharmaceutical composition containing such an antibody for regulating bone-forming activity in a mammal. Umansky provides no teaching or suggestion with regard to the utility of any fragments of SEQ ID NO:2 for generating antibodies for regulating bone-forming activity in a mammal. Finally, Umansky does not teach an antibody that is capable of inhibiting cell death mediated by overexpression of the polynucleotide set forth in SEQ ID NO:1.

In view of the remarks and amendments provided herein, Umansky fails to anticipate claims 1, 3-4, 6, and 20-25.

Claims 1, 3-4, 6, and 20-25 have been newly rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Rubin et al. (U.S. Patent No. 6,479,255) ("Rubin"). The Examiner states that Rubin teaches a polypeptide, such as an antibody capable of specifically binding an FRP polypeptide. Additionally, the Examiner states that Rubin teaches an FRP amino acid sequence

having 95.5% similarity to SEQ ID NO:2 of the instant application and the corresponding polynucleotide sequence with 97.4% similarity to SEQ ID NO:1 of the instant application.

The Examiner admits that Rubin does not teach a polypeptide or polynucleotide that is identical to those of the Applicants' and also does not expressly teach pharmaceutical compositions for regulating bone-forming activity in a mammal. The Examiner concludes, however, that this function would be inherent in the composition, since it allegedly has exactly the same components recited in the claims.

Claims 1, 20 and 22-24 have been amended as described above. As acknowledged by the Examiner, the FRP protein described by Rubin is not identical to the sFRP-1 protein of SEQ ID NO:2. Likewise, Rubin does not teach an antibody that is capable of inhibiting cell death mediated by overexpression of the polynucleotide set forth in SEQ ID NO:1. Thus, Rubin cannot anticipate the presently claimed antibodies. Finally, Rubin does not teach a pharmaceutical composition containing such an antibody for regulating bone-forming activity in a mammal. Thus, both Umansky and Rubin fail to anticipate claims 1, 3-4, 6, and 20-25. Reconsideration of claims 1, 3-4, 6, and 20-25 and withdrawal of the rejections of these claims under 35 U.S.C.§ 102(e) is requested.

C. Rejections under 35 U.S.C. §103(a)

Claim 2 has been newly rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,433, 155 ("Umansky"), in view of Warman et al. (WO 02/16553 A2, International publication date of February 28, 2002) ("Warman").

The Examiner cites Umansky for its teachings relating to a pharmaceutical composition comprising an antibody against a polypeptide of SARP. The Examiner concedes that Umansky does not disclose that SARP is from human osteoblast cells or that the bone-forming activity is the regulation of bone growth or bone density.

The Examiner relies on Warman for its teachings of sFRP-1 expression in purified trabecular bone primary cells, i.e., NHBC cells (human bone-derived cells). The Examiner states that Warman teaches sFRP-1 expression in different fractions of the primary cells which contain osteoblasts corresponding to different differentiation states (citing pg. 69, Example 8 and Fig. 8).

The Examiner reasons that it would have been obvious to one of ordinary skill in the art to combine the teachings of Umansky with those of Warman to prepare a pharmaceutical composition comprising an antibody against sFRP-1, wherein the sFRP-1 protein is from human osteoblast cells. The Examiner concludes that one of ordinary skill in the art would have been motivated to make such an antibody for the purpose of detecting the sFRP-1 protein in osteoblast cells and that the combined teachings of Umansky and Warman provide a reasonable expectation of success for preparing such a composition. (*See*, Office Action, page 7-8).

For a claim to be obvious under 35 U.S.C. § 103(a), all three of the following criteria must be satisfied:

1. there must be some suggestion or motivation to combine or modify the cited references;
2. there must be a reasonable expectation of success of combining or modifying the cited references; and
3. the combined references must teach each and every limitation of the claimed invention.

Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000). Applicant respectfully submits that these criteria have not been met, and thus traverse this rejection and request reconsideration of claim 2.

As discussed herein, claim 1 has been amended to recite "an antibody generated using a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2 as an immunogen for regulating bone-forming activity in a mammal." Dependent claim 2 further specifies that the sFRP-1 is from human osteoblast cells. The SARP proteins described by Umansky are not identical to the sFRP-1 protein of SEQ ID NO:2; therefore, Umansky fails to teach antibodies generated using an sFRP-1 protein of SEQ ID NO:2 as an immunogen. Thus, the combination of Umansky and Warman do not teach each and every limitation of the claimed invention.

Therefore, reconsideration of claim 2 and withdrawal of the rejection of this claim under 35 U.S.C.§ 103(a) is requested.

CONCLUSION

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: June 19, 2007

Respectfully submitted,

By Amy G. Klann

Amy G. Klann, Ph.D.
Registration No.: 48,155
DARBY & DARBY P.C.

P.O. Box 770
Church Street Station
New York, New York 10008-0770
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant